K023269

DEC 2 3 2002

Section 3
HemosIL High Sensitivity – C Reactive Protein
510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
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Contact Person:

Carol Marble, Regulatory Affairs Manager
Phone: 781-861-4467 / Fax: 781-861-4207

Summary Prepared:

September 30, 2002

Name of the Device:

HemosIL High Sensitivity – C Reactive Protein, AND
HemosIL High Sensitivity – C Reactive Protein Controls

Classification Name(s):

866.5270	C-Reactive Protein Immunological Test System	Class II
81DCK	C-Reactive Protein, Antigen, Antiserum, and Control	

Identification of predicate device(s):

K991385 N *High Sensitivity* CRP

Description of the device/intended use(s):

HemosIL High Sensitivity – C Reactive Protein is an *in vitro* diagnostic high sensitivity automated latex enhanced immunoassay for the quantitative determination of C Reactive Protein in human citrated plasma on IL Coagulation Systems. C Reactive Protein (CRP) aids in detecting and evaluating infection, tissue disorder, inflammatory disorders and associated diseases.

HemosIL High Sensitivity – C Reactive Protein Controls are assayed human serum controls intended to monitor the accuracy and precision of quantitative C Reactive Protein (CRP) assays.

The HS-CRP is a latex particle enhanced immunoturbidimetric assay to quantify CRP in plasma. When a plasma containing CRP is mixed with the Latex Reagent and the Reaction Buffer included in the kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of CRP in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates. The test range is well suited to cover apparent normality as well as the requirements as a marker of infectious and inflammatory diseases.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

HemosIL High Sensitivity – C Reactive Protein is substantially equivalent to the commercially available predicate device (N *High Sensitivity* CRP) in performance and intended use.

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Summary of Performance Data:

Method Comparison

In method comparison studies evaluating 153 samples with CRP levels ranging from 0.18 to 258 mg/L on an ACL 9000 and an ACL Futura, the slopes and correlation coefficients (r) for HemosIL High Sensitivity – C Reactive Protein versus the predicate device are shown below:

IL System	Slope	Intercept	r
ACL 9000	0.972	-0.070	0.9950
ACL Futura	0.942	-0.027	0.9945

Precision

Within run and total precision assessed over multiple runs using two levels of control gave the following results:

ACL 9000	Mean mg/L CRP	Within run CV%	Total CV%
Low HS-CRP Control	2.594	1.75	2.57
High HS-CRP Control	6.186	1.01	1.50

ACL Futura	Mean mg/dL CRP	Within run CV%	Total CV%
Low HS-CRP Control	0.255	3.04	3.42
High HS-CRP Control	0.607	3.42	3.63

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 3 2002

Ms. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Company
101 Hartwell Avenue
Lexington, MA 02421-3125

Re: k023269
Trade/Device Name: HemosIL High Sensitivity – C Reactive Protein AND
HemosIL High Sensitivity – C Reactive Protein Controls
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCK
Dated: December 16, 2002
Received: December 17, 2002

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: HemosIL High Sensitivity – C Reactive Protein AND
HemosIL High Sensitivity – C Reactive Protein Controls

Indications for Use:

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HemosIL High Sensitivity – C Reactive Protein Controls are assayed human serum controls intended to monitor the accuracy and precision of quantitative C Reactive Protein (CRP) assays.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023269

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.019)